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TRANSMITTAL FORM

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		Application Number	10/601,953
		Filing Date	6/24/2003
		First Named Inventor	Steven C. Quay
		Art Unit	1614
		Examiner Name	
Total Number of Pages in This Submission	19	Attorney Docket Number	02-03US

ENCLOSURES *(Check all that apply)*

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- [ ] Fee Attached
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PTO Form 1449 (15 pages) and copies of all references cited (1 box)
International Search Report (1 page)
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Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Nastech Pharmaceutical Company Inc.		
Signature			
Printed name	Peter J. Knudsen		
Date	November 21, 2005	Reg. No.	40682

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Typed or printed name	Jeffrey L. Granger	Date	November 21, 2005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Steven C. Quay	Attorney Docket No.: 02-03US
Serial No.: 10/601,953	Group Art Unit: 1614
Filed: 6/24/2003	
Title: COMPOSITIONS AND METHODS FOR MODULATING PHYSIOLOGY OF EPITHELIAL JUNCTIONAL ADHESION MOLECULES FOR ENHANCED MUCOSAL DELIVERY OF THERAPEUTIC COMPOUNDS	

Commissioner for Patents
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INFORMATION DISCLOSURE STATEMENT

Dear Sir:

This Information Disclosure Statement is submitted:

X under 37 CFR 1.97(b), or
(Within three months of filing national application; or date of entry of international application; or before mailing date of first office action on the merits; whichever occurs last)

___ under 37 CFR 1.97(c) together with either a:
___ Statement under 37 CFR 1.97(e), or
___ a $180.00 fee under 37 CFR 1.17(p), or
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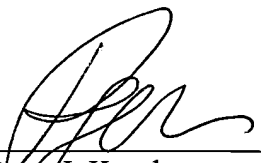
(Filed after final action or notice of allowance, whichever occurs first, but before payment of the issue fee)

X Applicant(s) submit herewith Form PTO 1449-Information Disclosure Citation together with copies, of patents, publications or other information of which applicant(s) are aware, which applicant(s) believe(s) may be material to the examination of this application and for which there may be a duty to disclose in accordance with 37 CFR 1.56.

The relevance of the attached references is that this is the closest art of which Applicant is aware. Applicant submits that the above references taken alone or in combination neither anticipate nor render obvious the present invention. Consideration of the foregoing in relation to this application is respectfully requested.

It is requested that the information disclosed herein be made of record in this application.

Respectfully submitted,



Peter J. Knudsen
Attorney/Agent for Applicant(s)
Reg. No. 40682

Date: November 21, 2005

Telephone No.: 425-908-3643

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	1	of	15

Complete if Known	
Application Number	10/601,953
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U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number: Number - Kind Code[2] (*if known*)	Issue Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 5,554,388	Issued 09-10-1996	Danbiosyst UK Limited	
		US- 5,629,011	Issued 05-13-1997	Danbiosyst UK Limited	
		US- 5,744,166	Issued 04-28-1998	Danbiosyst UK Limited	
		US- 5,935,604	Issued 08-10-1999	Danbiosyst UK Limited	
		US- 6,048,536	Issued 04-11-2000	Medeva Holdings BV	
		US- 6,110,747	Issued 08-29-2000	Adherex Technologies, Inc.	
		US- 6,136,606	Issued 10-24-2000	Medeva Holdings BV	
		US- 6,228,396	Issued 05-08-2001	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	
		US- 6,248,864	Issued 06-19-2001	Adherex Technologies, Inc.	
		US- 6,342,251	Issued 01-29-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	
		US- 6,391,318	Issued 05-21-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre	
		US- 6,383,513	Issued 05-07-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	

FOREIGN PATENT DOCUMENTS

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		WO 90/09780 (International Application Number PCT/GB90/00291)	09-07-1990	Danbiosyst UK Limited		
		WO 93/15737 (International Application Number PCT/GB93/00228)	08-19-1993	Danbiosyst UK Limited		
		WO 95/35100 (International Application Number PCT/GB95/01458)	12-28-1995	Danbiosyst UK Limited		
		WO 98/47535 (International Application Number PCT/GB98/01147)	10-29-1998	Danbiosyst UK Limited		
		WO 99/27905 (International Application Number PCT/GB98/03572)	06-10-1999	Danbiosyst UK Limited		
		WO 03/080021 (International Application Number PCT/GB03/01183)	10-02-2003	Ionix Pharmaceuticals Limited; West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited		

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		US- 6,387,917	Issued 05-14-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	
		US- 6,432,440	Issued 08-13-2002	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited	

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		WO 03/080022 (International Application Number PCT/GB03/01184)	10-02-2003	Ionix Pharmaceuticals Limited; West Pharmaceutical Services Drug Delivery & Clinical Research Centre Ltd.		
		WO 2004/062561 (International Application Number PCT/GB2004/000057)	07-29-2004	West Pharmaceutical Services Drug Delivery & Clinical Research Centre Limited		

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Sheet 3 of 15

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Application Number	10/601,953
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First Named Inventor	Quay
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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
		ARMSTRONG et al, "Clinical Modulation of Oral Leukoplakia and Protease Activity by Bowman-Birk Inhibitor Concentrate in a Phase IIa Chemoprevention Trial," *Clinical Cancer Research*, December 2000, vol. 6 no. 12, pages 4684-4691.	
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		FARRAJ et al, "Nasal Administration of Insulin Using Bioadhesive Microspheres as a Delivery System," *Journal of Controlled Release*, 1990, vol. 13, pages 253-261, Elsevier Science Publishers B.V., Amsterdam.	
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		KARLSSON et al, "Paracellular drug transport across intestinal epithelia: influence of charge and induced water flux," *European Journal of Pharmaceutical Sciences*, October 1999, vol. 9, no. 1, pages 47-56.	

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		DUIZER et al, "Absorption Enhancement, Structural Changes in Tight Junctions and Cytoxicity Caused by Palmitoyl Carnitine in Caco-2 and IEC-18 Cells," *The Journal of Pharmacology and Experimental Therapeutics*, October 1998, vol. 287, no. 1, pages 395-402.	
		BREWSTER et al, "The Effect of Dihydronicotinate N-Substitution on the Brain-Targeting Efficacy of a Zidovudine Chemical Delivery System," *Pharmaceutical Research*, 1993, vol. 10, no. 9, pages 1356-1362.	
		DREJER et al, "Intranasal Administration of Insulin With Phospholid as Absorption Enhancer: Pharmacokinetics in Normal Subjects," *Diabetic Medicine*, 1992, vol. 9, pages 335-340.	
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Sheet 5 of 15

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		TSUZUKI et al, "Adamantane as a Brain-Directed Drug Carrier for Poorly Absorbed Drug. 2. AZT Derivatives Conjugated with the 1-Adamantane Moiety," *Journal of Pharmaceutical Sciences*, April 1994, vol. 83, no. 4, pages 481-484.	
		WAKAMIYA et al, "Design and Synthesis of Peptides Passing through the Blood-Brain Barrier," *Bull. Chem. Soc. Jpn.*, 1998, vol. 71, pages 699-709.	
		THANOU et al, "Intestinal Absorption of Octreotide: *N*-Trimethyl Chitosan Chloride (TMC) Ameliorates the Permeability and Absorption Properties of the Somatostatin Analogue *In vitro* and *In vivo*," *Journal of Pharmaceutical Sciences*, July 2000, vol. 89, no. 7, pages 951-957.	
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		UCHIMAYA et al, "Enhanced Permeability of Insulin across the Rat Intestinal Membrane by Various Absorption Enhancers: Their Intestinal Mucosal Toxicity and Absorption-enhancing Mechanism of n-Lauryl-β-D-maltopyranoside," *J. Pharm. Pharmacol.*, November 1999, vol. 51, no. 11, pages 1241-1250.	
		LIU et al, "Structure-Activity Relationships for Enhancement of Paracellular Permeability by 2-Alkoxy-3-alkylamidopropylphosphocholines across Caco-2 Cell Monolayers," *Journal of Pharmaceutical Sciences*, November 1999, vol. 88, no. 11, pages 1169-1174.	
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		CREMASCHI et al, "Endocytosis of Polypeptides in Rabbit Nasal Respiratory Mucosa," *News Physiol. Sci.*, October 1997, vol. 12, pages 219-225.	
		HIRAI et al, "Mechanisms for the enhancement of the nasal absorption of insulin by surfactants," *International Journal of Pharmaceuticals*, 1981, vol. 9, pages 173-184, Elsevier/North-Holland Biomedical Press.	

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		ILLUM et al, "Bioadhesive microspheres as a potential nasal drug delivery system," *International Journal of Pharmaceutics*, 1987, vol. 39, pages 189-199, Elsevier Science Publishers B.V.	
		LEE et al, "Mucosal Penetration Enhancers For Facilitation of Peptide and Protein Drug Absorption," *Critical Reviews in Therapeutic Drug Carrier Systems*, 1991, vol. 8, no. 2, pages 91-192, CRC Press, Inc.	
		MISHIMA et al, "Studies on the Promoting Effects of Medium Chain Fatty Acid Salts on the Nasal Absorption of Insulin in Rats," *J. Pharmacobio-Dyn.*, 1987, vol. 10, pages 624-631.	
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		ROJANASAKUL et al, "The Transport Barrier of Epithelia: A Comparative Study on Membrane Permeability and Charge Selectivity in the Rabbit," *Pharmaceutical Research*, 1992, vol. 9, no. 8, pages 1029-1034, Plenum Publishing Corporation.	
		RYDÉN and EDMAN, "Effect of polymers and microspheres on the nasal absorption of insulin in rats," *International Journal of Pharmaceutics*, 1992, vol. 83, pages 1-10, Elsevier Science Publishers B.V.	
		SHEN et al, "Calu-3: a human airway epithelial cell line that shows cAMP-dependent Cl^- secretion," *Am. J. Physiol*, May 1994, vol. 266, no. 5 pt. 1, pages L493-501.	
		UCHIMAYA et al, "Effectiveness and Toxicity Screening of Various Absorption Enhancers in the Large Intestine: Intestinal Absorption of Phenol Red and Protein and Phospholipid Release from the Intestinal Membrane," *Biol. Pharm. Bull.*, 1996, vol. 19. no. 12, pages 1618-1621.	
		UCHIMAYA et al, "Effects of Various Protease Inhibitors on the Stability and Permeability of [D-Ala^2, D-Leu^5]enkephalin in the Rat Intestine: Comparison with Leucine Enkephalin," *Journal of Pharmaceutical Sciences*, April 1998, vol. 87, no. 4, pages 448-452.	
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Filing Date	6/24/2003
First Named Inventor	Quay
Art Unit	1614
Examiner Name	
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